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HALE & DORR LLP
THE WILLARD OFFICE BUILDING
1455 PENNSYLVANIA AVE, NW
WASHINGTON, DC 20004

EXAMINER

GILLIGAN, CHRISTOPHER L

ART UNIT PAPER NUMBER

3626

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,205

Applicant(s)

ROVINELLI ET AL.

Examiner

Luke Gilligan

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-52 is/are pending in the application.
- 4a) Of the above claim(s) 44,45 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-43,46-48 and 52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

1. Applicant's election without traverse of Group I including claims 2-43, 46-48, and 52 in Paper No. 20 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 41-43, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Harless, U.S. Patent No. 5,006,978.
4. As per claim 41, Harless teaches a computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, said method comprising the steps of: (a) generating an initial patient history state, wherein said initial patient history state comprises a predetermined set of health states (see column 4, lines 26-30, the "significant past experiences" is taken to include all of the relevant predetermined health states); (b) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions (see column 7, lines 56-61); (c) evolving the initial patient history state to a predetermined subsequent patient history health state responsive to said at least one intervention (see column 8, lines 61-66); and (d) evaluating said user responsive to said at least one intervention (see column 9, lines 31-35).

Art Unit: 3626

5. As per claim 42, Harless teaches the method of claim 41 as described above, wherein evolving the initial patient history state to said predetermined subsequent patient history state occurs over a finite stochastically determined time period (see column 7, lines 61-67).

6. As per claim 43, Harless teaches the method of claim 41 as described above, further comprising the step of repeating said evolving step and receiving step a plurality of times (see column 9, lines 1-7).

7. As per claim 46, Harless teaches a computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, said method comprising the steps of: (a) generating multiple instances of patients representing a clinical scenario (see column 3, lines 28-32), wherein each instance of a patient has an initial patient history state comprising a predetermined set of health states (see column 4, lines 26-30, the "significant past experiences" is taken to include all of the relevant predetermined health states); (b) evolving at least one of each instance of said patient's initial patient history state to a predetermined subsequent patient history health state (see column 8, lines 61-66); (c) receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions (see column 7, lines 56-61); and (d) evaluating said user responsive to said at least one intervention (see column 9, lines 31-35).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3626

9. Claims 40, 2-25, 27, 29, 34, 37-39, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harless, U.S. Patent No. 5,006,978 in view of Gillo, U.S. Patent No. 5,882,206.

10. As per claim 40, Harless teaches a computer implemented simulation and evaluation method for testing a user's problem solving abilities in response to a complex system, said method comprising the steps of: selecting a testing area to evaluate said user on at least one predetermined criterion (see column 10, lines 14-25); selecting epidemiological information including at least one of genetic information and environmental information of a patient responsive to said testing area (see column 4, lines 26-30); generating a patient history responsive to said testing area and said epidemiological information including said at least one of genetic information and environmental information, wherein said patient history comprises a predetermined set of health states (see column 4, lines 26-30, the "significant past experiences" is taken to include all of the relevant predetermined health states); receiving at least one intervention input by said user, wherein said at least one intervention includes passive and active interventions (see column 7, lines 56-61); and evaluating said user responsive to said at least one predetermined criteria and said at least one intervention (see column 9, lines 31-35). Harless does not explicitly teach accessing a profile for said user. Gillo teaches accessing a user profile for a user being evaluated on interaction with a simulated patient (see column 13, lines 36-41). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make such a modification for the purpose of better tailor the testing to the individual test taker.

11. As per claim 2, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches evolving the patient to a predetermined health state responsive

Art Unit: 3626

to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (See column 8, lines 61-66); and evaluating the user responsive to the at least one intervention input by the user, the at least one subsequent health state, and the predetermined criteria (see column 10, lines 14-25).

12. As per claim 3, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches evolving the patient to a predetermined health state responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (See column 8, lines 61-66); receiving at least one other intervention input by the user (see column 7, lines 56-61); and evaluating the user responsive to the at least one intervention input by the user, the at least one other intervention input by the user, the at least one subsequent health state, and the predetermined criteria (see column 10, lines 14-25).

13. As per claim 4, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches evolving the patient to a predetermined health state responsive to the at least one intervention, the genetic information and the patient history to at least one subsequent health state (See column 8, lines 61-66); receiving at least one other intervention input by the user (see column 7, lines 56-61); evolving the patient responsive to the at least one intervention, the genetic information and the patient history to at least one other subsequent health state (see column 8, lines 61-66) and evaluating the user responsive to the at least one intervention input by the user, the at least one other intervention input by the user, the at least one subsequent health state, and the predetermined criteria (see column 10, lines 14-25).

14. As per claim 5, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches the generating step further comprises the step of generating the patient history responsive to the test area, the genetic information, and an entity relationship model (see column 4, lines 26-30).

Art Unit: 3626

15. As per claim 6, Harless in view of Gillo teach the method of claim 5 as described above.

Harless further teaches the entity relationship model comprises population, record agents of change, health states, findings and courses of action (see column 7, lines 12-16).

16. As per claim 7, Harless in view of Gillo teach the method of claim 6 as described above.

Harless further teaches the findings include specific findings, patterns and sub-patterns describing patient behaviors and characteristics (see column 4, lines 17-25).

17. As per claim 8, Harless in view of Gillo teach the method of claim 7 as described above.

Harless further teaches the patterns described one or more features over time (see column 4, lines 26-33).

18. As per claim 9, Harless in view of Gillo teach the method of claim 7 as described above.

Harless further teaches the sub-patterns describe consequences of patient related events (see column 4, lines 17-25).

19. As per claim 10, Harless in view of Gillo teach the method of claim 7 as described

above. Harless further teaches the patterns model time and characterize interrelated medical observations (see column 7, lines 12-16).

20. As per claim 11, Harless in view of Gillo teach the method of claim 7 as described

above. Harless further teaches performing a differential diagnosis responsive to the findings, the patterns and the sub-patterns (see column 7, lines 53-55).

21. As per claim 12, Harless in view of Gillo teach the method of claim 7 as described

above. Harless further teaches the confidence in a presence of the patterns increases with the passage of time (see column 7, lines 56-61).

22. As per claim 13, Harless in view of Gillo teach the method of claim 6 as described

above. Harless further teaches the courses of action describe tasks and methods used to

Art Unit: 3626

apply, modify, and evaluate health state information and characteristics described in the entity relationship model (see column 7, lines 19-25).

23. As per claim 14, Harless in view of Gillo teach the method of claim 6 as described above. Harless further teaches the courses of action describe patient activities, including at least one of medical and non-medical activities (see column 8, lines 51-60).

24. As per claim 15, Harless in view of Gillo teach the method of claim 6 as described above. Harless further teaches the courses of action describe potential interventions input by the user including at least one of diagnostic and management strategies (see column 7, lines 19-56).

25. As per claim 16, Harless in view of Gillo teach the method of claim 6 as described above. Harless further teaches the courses of action comprise one or more elementary courses of action used to construct at least one course of action, one or more types of elementary action corresponding to the one or more elementary course of action, and weighting factors corresponding to the one or more elementary courses of action (see column 7, lines 12-19, the "likelihood" comprises the weighting factors).

26. As per claim 17, Harless in view of Gillo teach the method of claim 5 as described above. Harless further teaches the entity relationship model includes entity relations (see column 4, lines 26-30).

27. As per claim 18, Harless in view of Gillo teach the method of claim 17 as described above. Harless further teaches evolving the patient responsive to the at least one intervention, the genetic information, the entity relations and the patient history to at least one subsequent health state (see column 8, lines 61-66).

Art Unit: 3626

28. As per claim 19, Harless in view of Gillo teach the method of claim 5 as described above. Harless further teaches the entity relationship model includes health states leads to health states relation describing patient evolution (see column 61-66).

29. As per claim 20, Harless in view of Gillo teach the method of claim 5 as described above. Harless does not explicitly teach the entire list of relationships listed in claim 20. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include any one of the specific relationships listed in claim 20. One of ordinary skill in the art would have been motivated to do this for the purpose of observing changes in one entity caused by changes in another.

30. As per claim 21, Harless in view of Gillo teach the method of claim 6 as described above. Harless further teaches the entity relationship model links the findings with the patterns to a health state, rather than linking a range of finding values to the health state (see column 7m lines 25-33).

31. As per claim 22, Harless in view of Gillo teach the method of claim 6 as described above. Harless further teaches the patterns include sensitivity and specificity represented as age dependent, rather than as constants (see column 4, lines 19-25).

32. As per claim 23, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches generating the patient history is executed once for each simulation to generate the patient history used in said computer implemented simulation and evaluation method (see column 3, lines 28-32).

33. As per claim 24, Harless in view of Gillo teach the method of claim 2 as described above. Harless further teaches repeating said evolving step and receiving step a plurality of times (see column 9, lines 1-7).

Art Unit: 3626

34. As per claim 25, Harless in view of Gillo teach the method of claim 40 as described above. Harless further teaches generating the patient history comprising a progression of health states and risk factors traversed by the patient from a normal health condition to a specified health condition (see column 8, lines 35-43).

35. As per claim 27, Harless in view of Gillo teach the method of claim 40 as described above. Harless does not explicitly teach using a Monte Carlo process to multiple stochastic trees to generate a plurality of potential patient histories to be used in said computer implemented simulation and evaluation method. However, Monte Carlo process is old and well known in the art of statistical analysis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a Monte Carlo process to generate a plurality of potential patient histories for use in the simulation and evaluation method of Harless for the purpose of comparing multiple patient histories for the same patient.

36. As per claim 29, Harless in view of Gillo teach the method of claim 5 as described above. Harless further teaches the entity relationship model includes diagnostic complexities and disease interaction (see column 7, lines 38-42).

37. As per claim 34, Harless in view of Gillo teach the method of claim 2 as described above. Harless further teaches repeating said evolving step to the at least one subsequent health state is responsive to: parallel health states of the patient (see column 8, lines 35-43); and a target health state and health state combinations that lead to different parallel states (see column 8, lines 35-43).

38. Claims 37-39 contain substantially similar limitations to method claim 40 and, as such, are rejected for similar reasons as given above.

39. As per claim 48, Harless teaches a computer implemented method for evaluating a user's response to a simulated patient, said method comprising the steps of: selecting subject

Art Unit: 3626

matter on which to evaluate said user (see column 10, lines 14-25); generating a first target health state of a simulated patient (see column 4, line 26-30); generating a medical history for said simulated patient (See column 4, lines 26-30); presenting said simulated patient to said user (see column 4, lines 64-68); receiving at least one query including at least one of an interactive and a request for additional information regarding the patient from said user in response to said first target health state (see column 7, lines 56-61); evolving said first target health state forward in time in response to said at least one query to a second target health state (see column 8, lines 61-66); and evaluating said user based on said at least one query (see column 9, lines 31-35). Harless does not explicitly teach accessing a profile for said user. Gillo teaches accessing a user profile for a user being evaluated on interaction with a simulated patient (see column 13, lines 36-41). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make such a modification for the purpose of better tailor the testing to the individual test taker.

40. Claims 28, 30-33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harless, U.S. Patent No. 5,006,978 in view of Gillo, U.S. Patent No. 5,882,206 and further in view of Fink et al., U.S. Patent No. 5,657,255.

41. As per claim 28, Harless in view of Gillo teach the method of claim 5 as described above. Harless does not explicitly teach the entity relationship model utilizes tree structures to describe a probability density function conditioned on comorbidities, treatments, risk factors, and the interventions. Fink teaches the entity relationship model utilizes tree structures to describe a probability density function conditioned on comorbidities, treatments, risk factors, and the interventions (see column 7, lines 54-67). It would have been obvious to one of ordinary skill in

Art Unit: 3626

the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make such a modification for the purpose of enhancing the level of detail for the generated patient simulation.

42. As per claim 30, Harless in view of Gillo teach the method of claim 5 as described above. Harless does not explicitly teach the entity relationship model includes parallel networks of health states to avoid combinatoric health state explosion. Fink teaches the entity relationship model includes parallel networks of health states to avoid combinatoric health state explosion (see column 12, lines 4-8). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make such a modification for the purpose of enhancing the level of detail for the generated patient simulation.

43. As per claim 31, Harless in view of Gillo and Fink teach the method of claim 30 as described above. Fink further teaches the parallel networks of health states describe at least one of a chronic condition and non-chronic condition (see column 12, lines 19-21, any set of conditions could be linked). It would have been obvious to one of ordinary skill in the art of patient simulation to incorporate this feature into the system of Harless for the reasons given above with respect to claim 30.

44. As per claim 32, Harless in view of Gillo and Fink teach the method of claim 30 as described above. Fink further teaches the non-chronic condition includes acute exacerbations describing acute flares of illness that occur during a more chronic health condition (see column 12, lines 19-21, any set of conditions could be linked). It would have been obvious to one of ordinary skill in the art of patient simulation to incorporate this feature into the system of Harless for the reasons given above with respect to claim 30.

Art Unit: 3626

45. As per claim 33, Harless in view of Gillo and Fink teach the method of claim 30 as described above. Fink further teaches the parallel networks of health states form at least one of the following interactions: independent interaction between the parallel networks so that patient evolution between first and second parallel networks are unrelated to each other; unilateral interaction between the parallel networks so that patient evolution on a first parallel network is unrelated to the patient evolution on a second parallel network, and patient evolution on the second parallel network is related to the patient evolution on the first parallel network; and mutually dependent interaction between the parallel networks so that patient evolution between the first and second parallel networks are related to each other (see column 9, lines 42-49). It would have been obvious to one of ordinary skill in the art of patient simulation to incorporate this feature into the system of Harless for the reasons given above with respect to claim 30.

46. As per claim 35, Harless in view of Gillo and Fink teach the method of claim 30 as described above. Fink further teaches the parallel networks of health states comprise: a primary network including primary health conditions defining a health domain (see column 12, lines 25-27); a risk factor network including risk factors for progression through the primary network (see column 12, lines 27-29); and complications attributed to treating the primary health conditions in the primary network (see column 12, lines 10-13). It would have been obvious to one of ordinary skill in the art of patient simulation to incorporate this feature into the system of Harless for the reasons given above with respect to claim 30.

47. As per claim 36, Harless in view of Gillo and Fink teach the method of claim 35 as described above. Fink further teaches the parallel networks of health states are generated using the following information: how long at least one of the risk factors exists before influencing a transition between primary health conditions in the primary network (see column 3, lines 15-17); time required for transitions in the primary network, considering different combinations of

Art Unit: 3626

the risk factors (see column 3, lines 17-20); and number of transitions the patient is allowed to make between a specified health state and a normal health state (see column 13, lines 18-20, it is assumed that the clinical result would include the number of transitions the patient will make).

48. Claims 26, 47, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harless, U.S. Patent No. 5,006,978 in view of Herren et al., U.S. Patent No. 6,108,635.

49. As per claim 26, Harless in view of Gillo teach the method of claim 40 as described above. Harless does not explicitly teach iteratively generating the patient history backwards in time from a specified health condition to a normal health condition including successive precursor health states and onset times. Herren teaches generating a patient history backwards in time from a specified health condition to a normal health condition including successive precursor health states and onset times (see column 7, lines 42-46). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make this modification for the purpose of enhancing the ability to realistically generate histories for the simulated patients presented. Moreover, Herren suggests combining the system with other systems (see column 8, lines 14-17).

50. As per claim 47, Harless teaches a computer implemented method for evaluating a user's response to a simulated patient, said method comprising: selecting subject matter on which to evaluate a user (see column 4, lines 17-25); generating a first target health state of a patient, wherein said first target health state is determined by said subject matter (see column 4, lines 26-30); generating a medical history for said patient (see column 4, lines 26-30); receiving at least one query including at least one of an intervention and a request for additional information regarding the patient from said user in response to said first target health state (see

Art Unit: 3626

column 7, lines 56-61); evolving said first target health state forward in time in response to said at least one query to a second target health state (see column 8, lines 61-66); and evaluating said user based on said at least one query (see column 9, lines 31-35). Harless does not explicitly teach generating said medical history comprises iterating from said first target health state backward in time through at least one precursor health state to an initial health state. Herren teaches generating a medical history for a simulated patient by iterating from a first target health state backward in time through at least one precursor health state to an initial health state (see column 7, lines 42-46). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make this modification for the purpose of enhancing the ability to realistically generate histories for the simulated patients presented. Moreover, Herren suggests combining the system with other systems (see column 8, lines 14-17).

51. As per claim 52, Harless teaches a computer simulated method for evaluating the problem solving skills of a user, said method comprising: selecting subject matter on which to evaluate said user (see column 4, lines 17-25); generating a first problem environment, wherein said first problem environment is determined by said subject matter (see column 4, lines 26-30); generating a history of said first problem environment (see column 4, lines 26-30); receiving at least one query including at least one of an intervention and a request for additional information from said user in response to said first problem environment (see column 7, lines 56-61); evolving said first problem environment forward in time in response to said at least one query to a second problem environment (see column 8, lines 61-66); and evaluating said user based on said at least one query (see column 9, lines 31-35). Harless does not explicitly teach generating said first problem environment comprises iterating from said first situation backward in time

Art Unit: 3626

through at least one precursor situation to an initial situation. Herren teaches generating a medical history for a simulated patient by iterating from a first target health state backward in time through at least one precursor health state to an initial health state (see column 7, lines 42-46). It would have been obvious to one of ordinary skill in the art of patient simulation at the time of the invention to incorporate this feature into the system of Harless. One of ordinary skill in the art would have been motivated to make this modification for the purpose of enhancing the ability to realistically generate histories for the simulated patients presented. Moreover, Herren suggests combining the system with other systems (see column 8, lines 14-17).

Conclusion

52. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Woolf discloses a system for simulating a patient in the emergency room and responding in real-time to input interventions.

53. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (703) 308-6104. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

54. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

55. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.


Application/Control Number: 09/759,205

Page 16

Art Unit: 3626


CLG

June 2, 2003


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600